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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/284,935      | 05/03/1999  | MINORU TAKEBE        | 211A-2828-PC        | 3005             |

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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/284,935             | TAKEBE ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Vera Afremova          | 1651                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7 and 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Claims 1, 2, 5, 7 and 9-11 as amended (4/02/2004) are pending and under examination.

Claims 3, 4, 6 and 8 were canceled by Applicants {papers filed on 7/09/2003 and on 4/17/2001}.

### ***Claim Rejections - 35 U.S.C. § 112***

#### ***Indefinite***

Claims 1, 2, 5, 7 and 9-11 as amended remain/are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as explained in the prior office action.

Claims 1, 2 and 5 remain/are indefinite with respect to the phrase “a substance that will not be digested and absorbed...”. This “substance” is required to be present in the claimed product or in “material” obtained by the claimed method. However, applicants do not provide specific definitions about the nature of this substance. The method as claimed does not require separation, recovery or purification of the intended “substance” from the final fermentate of unknown chemical structure or unknown contents. According to the generic disclosure, the claimed undigested “substance” appears to be “enzyme undecomposed substance” (see specification page 7, line 1). Thus, in the instant office action the claimed “substance” is interpreted as some substance that could be present in the material produced by koji fungal culture enzymatic fermentation of grains.

Claims 1, 2 and 5 remain/are indefinite with respect to the phrase “decomposing a phytic acid”. The claimed invention neither indicate how much of phytic acid is removed and/or left in the “resultant” nor it requires a total removal of phytic acid. The specification does not indicate

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how much of phytic acid would be decomposed or left in the resultant. Thus, the meaning of the phrase “decomposing a phytic acid” is interpreted in a broadest sense as a natural koji mold grain fermentation process or an inherent event during fermentation of grains by koji molds because the koji molds have phytase and phosphatase which are enzymes decomposing phytic acid as taught by US 5,885,632 (paragraph bridging col. 8 and col. 9).

### ***Double Patenting***

The terminal disclaimer filed 4/02/2004 has been entered.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5, 7, 9 and 11 as amended remain rejected under 35 U.S.C. 102(e) as being anticipated by US 5,885,632 as explained in the prior office action and repeated herein.

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, cooling grains, inoculating the grains with koji molds, adding water, cultivating the koji molds with pre-existing or added beneficial microorganisms and “decomposing” phytic acid. The claimed beneficial microorganisms are representatives of *Eumycetes* which are fungal cultures including koji molds. The intended effects of the claimed material are health-sustaining effects related to propagation of beneficial microorganisms on the material. The claimed fermented product comprises “a substance that will not be digested and absorbed in small intestines”. Some claims are further drawn to adding water in amounts to reach the water content of 50% by weigh.

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US 5,885,632 teaches a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating grains or crops such as soybeans with koji mold to create a koji preparation resultant, adding water to the resultant and removing phytic acid (see fig. 1; col. 4, lines 35-45 and lines 52-57) wherein that additional beneficial microorganisms contained (pre-existing) in the resultant are also koji mold preparations, for example: col. 6, lines 43-45. The phytic acid is decomposed in the method of US'632 to some "predetermined" amount within the meaning of the instant claims (col. 9, lines 34-37 and table 4). The effects of the US' 632 product are health-promoting effects related to propagation of beneficial microorganisms and/or other health-promoting effects such as carcinopreventive (see abstract). The amount of water which is added and/or present during hydrolysis is at least 40% by weight and more (col. 6, line 25) as required by the presently claimed invention.

With respect to claim 7 it is noted that the taxonomic group of *Eumycetes* comprises all fungi including yeasts and koji molds belonging to *Aspergillus* (see Ainsworth & Bibsy's Dictionary of the Fungi at page 158). Thus, regardless the fact that some other microbial species might be intended, the method of the cited patent US'632 utilizes the same microorganisms as the claimed invention including representatives of *Eumycetes* that are koji molds or *Aspergillus*.

Thus, the fermentation and hydrolysis process as disclosed by US'632 is identical to the claimed process because both processes comprise identical active steps and identical materials. Therefore, the final fermented and hydrolyzed products are identical because they are obtained by identical methods. Although the cited US'632 is silent with regard to the "substance that will not be digested ...", this substance is inherently present in the final fermented/hydrolyzed product of US'632 because the US'632 protocol of making is identical to the presently claimed

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invention, particularly in view that the nature of this "substance" is not clearly identified by the instant application and claims.

Therefore, US 5,885,632 anticipates the claimed invention.

Claims 1, 5 and 7 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by US 4,308,284 in the light of evidence provided by teaching of US 5,885,632 as explained in the prior office action and repeated herein.

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, cooling grains, inoculating the grains with koji molds, adding water, cultivating the koji molds with pre-existing or added beneficial microorganisms and "decomposing" phytic acid. The claimed beneficial microorganisms are representatives of *Eumycetes* (yeasts) and lactic bacteria. The intended effects of the claimed material are health-sustaining effects related to propagation of beneficial microorganisms on the material. The claimed fermented product comprises "a substance that will not be digested and absorbed in small intestines".

US 4,308,284 teaches a process and a product obtained by the process comprising steps of cooking and cooling grains or soybeans, inoculating the grains with koji mold belonging to *Aspergillus*, adding aqueous suspension with two additional groups of beneficial microorganisms including yeasts *Saccharomyces* and lactic bacteria *Rediococcus*, fermenting and hydrolyzing the grains with three types of microorganisms including koji molds, yeasts and lactic bacteria. See disclosure at col. 7, lines 5-25.

The step of decomposing phytic acid which is contained in the grains or hydrolyzed resultant is inherently present in the method/composition-obtained-by-method of the cited patent '284 in the light of evidence as taught by US 5,885,632. For example: the teaching of US 5,885,632 demonstrates that koji molds have phytase and phosphatase (enzymes decomposing phytic acid) and that phytic acid is decomposed and/or removed during koji mold fermentation in

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the presence of water (see US'632 col. 9, lines 15 and col.8, lines 60-67). The cited US'284 encompasses the use of identical koji mold fungal cultures, the use of identical grains in the presence of water and/or added water at least in a form of aqueous suspension. Therefore, the event or the step of "decomposing" phytic acid is considered as a natural process or an inherent event in the method and composition-obtained-by-methods disclosed by US'284. Thus, the disclosure of US 4,308,284 appears to anticipate the presently claimed invention because it encompasses identical components in the final product and identical steps in the method of making the product as presently claimed. Although the cited US'284 is silent with regard to the "substance that will not be digested ...", this substance is inherently present in the US'284 final complex fermented and hydrolyzed product obtained by the process identical to the claimed process, particularly in view that the nature of this "substance" is not clearly identified by the instant application and claims. The beneficial microorganisms are propagated on the fermented grains as disclosed by US'284 and thus, the effects that are intended by the instant claims and related to obtaining making material for promoting growth of beneficial microorganisms, appear to be achieved by the protocol as disclosed by US'284.

Therefore, US 4,308,284 anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5, 7, 9 and 11 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,885,632 and US 4,308,284 and US 4,329,370 as explained in the prior office action and repeated herein.

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, inoculating grains with koji molds, adding water,

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cultivating the koji molds with beneficial microorganisms and decomposing phytic acid. The intended effects of the claimed material are health-sustaining effects related to propagation of beneficial microorganisms on the material. Some claims are further drawn to the use of beneficial microorganisms such as yeasts belonging to *Eumycetes* and lactic bacteria or bifidobacteria. Some claims are further drawn to the use of water content such as about 50%.

The cited patent US 5,885,632 is relied upon for the disclosure of a product and a product obtained by process wherein the process encompasses fermentation and hydrolysis of grains with 1 group of microorganisms that are koji molds originally present in non-sterile grain material and/or added to grain materials and wherein the process encompasses addition of water to reach at least 40 % weight amount.

The cited patent US 4,308,284 is relied upon for the disclosure of a product and a product obtained by process wherein the process encompasses fermentation and hydrolysis of grains with 3 groups of microorganisms including koji molds, yeasts and lactic bacteria. The process encompasses addition of some water but the cited patent is silent with particular amount of water added.

However, US 4,329,370 teaches that koji molds fermentations generally encompass the use of about 40-50% of water (col. 2, lines 61-62). The reduction of water content would reduce amount of additional and/or contaminating bacteria (col. 2, lines 25-35).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was to adjust amounts of water to 50 % during fermentation and hydrolysis of grains by koji molds with a reasonable expectation in success in obtaining koji mold fermented materials because these amounts are generally used in koji fermentation of



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grains as clearly taught and/or suggested by US 5,885,632. One of skill in the art would have been motivated to add water to the materials under fermentation by several groups of microbes as in the method of US 4,308,284 so as to reach amounts of 50 % or no less than 40% in order to avoid inhibition of additional bacteria as clearly taught by US 5,965,178. The reduction of water content would reduce viability of additional bacteria and, thus, fermentations that require viability of several groups of microorganisms including koji molds and bacteria are reasonably expected to need addition of 50 % of water as it is encompassed by the presently claimed invention. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 1, 2, 5, 7 and 9-11 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,885,632 and US 4,308,284 and US 4,329,370 as applied to claims 1, 5, 7, 9 and 11 above, and further in view of WO 96/08261 as explained in the prior office action and repeated herein.

Claims 1, 5, 7, 9 and 11 as explained above. Some claims are further drawn to incorporation of resistant starch into the product obtained by the claimed process.

The cited documents US 5,885,632; US 4,308,284 and US 4,329,370 are relied upon as explained above. They are lacking disclosure related to incorporation of resistant starch into the product obtained by the claimed process.

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However, the cited WO 96/08261 teaches that resistant starch is a suitable carrier for beneficial microorganisms including lactic bacteria and that resistant starch acts as a growth-promoting medium for beneficial microorganisms including lactic bacteria in the large bowel of the gastrointestinal tract (see abstract or page 3). WO 96/08261 teaches addition of resistant starch to the beneficial health promoting products intended to provide for grow and propagation of probiotics including lactic bacteria.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was to add resistant starch to the products intended for propagation and growth of beneficial bacteria with a reasonable expectation in success in obtaining beneficial probiotic compositions as adequately taught by WO 96/08261. One of skill in the art would have been motivated to add resistant starch to the products with beneficial microorganisms for the expected health related beneficial effects provided by probiotics including lactic bacteria in the gastrointestinal tract particularly in large bowel as taught by WO 96/08621 (page 1, lines 25-30). Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

### ***Response to Arguments***

Applicant's arguments filed 4/02/2004 have been fully considered but they are not persuasive for the reasons below.

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With respect to the cited patents US 5,885,632 and US 4,308,284 applicants main argument is directed to the idea that they do not teach and/or suggest “a substance that will not be digested and absorbed...”. However, the instant invention does not provide clear definitions about the nature of the claimed substance. The final product as claimed is a fermented product of unknown chemical structure and contents. Thus, the fermented products of unknown structure and contents of the cited patents are considered to include the same “substance” as the claimed product within the broadest meaning of the claims because the cited products are made by koji mold fermentation of grains wherein the materials used and protocols of treatments are identical to the materials and protocols as claimed.

With respect to the cited patent US 4,308,284 applicants also argue that it does not clearly indicate step of “decomposing” phytic acid. Yet, the final product as claimed is not required to be totally free of phytic acid. The method as claimed does not point out what is a particular protocol of “decomposing” and/or how much of phytic acid is removed from or left in the final product. Thus, in the light of evidence by US 5,885,632 that demonstrates that koji molds have phytase and phosphatase (enzymes decomposing phytic acid), the “decomposing” phytic acid is an inherent event in the method of in the cited US 4,308,284.

With respect to the cited WO'261 applicants appear to argue that it teaches addition of resistant starch to a mixture of freeze-dried probiotic microorganisms but not the addition of resistant starch to a “fermentation product”. This is not found persuasive because the cited document clearly teaches the use of resistant starch as a carrier that helps to deliver an active ingredient to the large bowel and, thus, to pass through the small intestine without being digested and/or absorbed at least in the upper GI. Moreover, the final product as claimed contains live

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“beneficial microorganisms” that are the same as probiotics. Thus, one of skill in the art would have been motivated to add resistant starch to the fermented products comprising “beneficial microorganisms” for the expected health related beneficial effects provided by probiotics in GI and particularly in large bowel as taught by WO 96/08621.

No claims are allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

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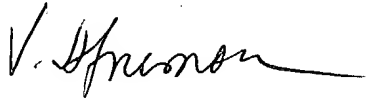
The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Vera Afremova

AU 1651

June 15, 2004

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PATENT EXAMINER